Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume XIII Issue 3 April/May 2008

Laboratory Quality Assurance (LQA) Update

by Susan Walker, DOH/LQA

Laboratory Quality Assurance (LQA) is part of the Health Systems Quality Assurance (HSQA) Division of the Washington State Department of Health. The Division is undergoing changes that will affect the way we do business.

New Computer System: HSQA has implemented a new computer system that integrates professional and facility licensing. This integration changes the way we do business in LQA. You should be aware of the following changes.

MTS/CLIA Licenses: The MTS/CLIA licenses issued by the new computer system will look different. All of the information found on the current license is on the new license. Please note that your MTS license number has also changed. It is now an eight-digit number.

Calling LQA for Assistance: Please have your MTS license number and/or CLIA number available when you call LQA with questions about your license. This will help us give you more rapid assistance. Your MTS license number and CLIA number are found on your MTS license.

MTS license numbers will look different. They will be eight-digit numbers preceded by the MTS license category. This is an example of a Certificate of Waiver license number (MTSW.FS.XXXXXXXX).

MTS/CLIA License Applications: There are now four different MTS license application forms available on the LQA website (http://doh.wa.gov/lqa.htm) or from our office (call 206- 418-5600). Mail new MTS license applications to the Tumwater address for initial processing. Please do not use old versions of the MTS license application. The four types of MTS licenses are:

- **Certificate of Waiver (MTSW)**
  - Include the biennial license fee with your application.
  - Site can only perform tests listed on the Food and Drug Administration (FDA) waived test list.

continued on page 7

Inside This Issue

Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

Anemia	Lipid Screening
ANA	PAP Smear
Bioterrorism Event Mgmt	Point-of-Care Testing
Bleeding Disorders	PSA
Chlamydia	Rash Illness
Diabetes	Red Cell Transfusion
Group A Strep Pharyngitis	Renal Disease
Group B Streptococcus	STD
Hepatitis	Thyroid
HIV	Tuberculosis
Infectious Diarrhea	Urinalysis
Intestinal Parasites	Wellness

Public Health Laboratories Microbiology Unit: New Specimen Submitter Forms

by Craig Colombel, DOH/PHL

The Washington State Public Health Laboratories (PHL) Microbiology Unit is changing and consolidating submitter requisition forms. We reduced the submitter requisition forms from eleven (11) to five (5).

Use the "**Microbiology**" form for Reference Bacteriology, Molecular Diagnosis/PCR, Clinical Mycobacteriology (clinical TB and MTD only orders), Parasitology, Enteric, Nose and Throat, and Fluorescent Microbiology units. See page 3 for an example of this new form.

Use the **"Serology/Virology/HIV"** form for Viral Serology, Syphilis Serology, Virology Culture, and HIV units. See page 4 for an example of this new form.

If you are a TB core lab or a lab that sends TB reference isolates to the PHL TB unit, the ***"Mycobacteriology tuberculosis* Isolates"** form will still be used. See page 5 for an example of this form.

The Chlamydia and Rabies forms remain the same.

Decreasing the number of separate forms needed for submitting specimens to the PHL is a definite advantage for our clients. The new forms are standard paper size (8.5 x 11 inches) with general instructions on the back. The larger forms make them easier to complete and to copy.

The forms are currently available on the PHL web site in a PDF format that you can download and copy. The PHL is sending the new forms with kit requests. The PHL website is: http://www.doh.wa.gov/EHSPHL/PHL/microbiology/Microbiology.htm. The PDF format allows the PHL microbiology unit to make changes quickly and get the updated forms to you in a rapid manner. See pages 3-5 for examples of the new forms.

The PHL will no longer accept the old forms after **December 31, 2008**. We welcome any comments and questions about the new forms. Please direct your questions and comments to:

Craig Colombel
Phone: 206-418-5474
Email: craig.colombel@doh.wa.gov

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NOTE: Letters to the editor may be published unless specified otherwise by the author.

Website addresses:
DOH home page: http://www.doh.wa.gov
LQA home page: http://www.doh.wa.gov/lqa.htm
PHL home page:
http://www.doh.wa.gov/EHSPHL/PHL/default.htm

PHL Website Information

The PHL website has many resources available on its website. The website address for the PHL is: http://www.doh.wa.gov/EHSPHL/PHL/default.htm. Information found on the website includes:

- PHL Office/Laboratories/Units
- Training Program
- PHL Laboratory Services
- Current Projects
- Packing and Shipping Information
- Frequently Asked Questions
- Links
- Driving Instructions
- Glossary of Terms and Acronyms
- Contact Information
- PHL Directory of Services
- Elaborations Newsletter
- Brochures

Washington State Department of Health
Public Health Laboratories

State of Washington
Department of Health
PUBLIC HEALTH LABORATORIES
1610 N.E. 150th Street
Shoreline, Washington 98155-9701
Phone: (206) 418-5400
Fax: (206) 418-5545
MTS #1327 CLIA #50D0661453
Http://WWW.DOH.WA.GOV/EHSPHL/PHL

FOR PHL USE ONLY

Lab Number Date/Time Received

Please Print Clearly

MICROBIOLOGY

PATIENT

NAME (LAST)

(FIRST) (MI)

ADDRESS

CITY STATE ZIP CODE

MALE ○ FEMALE ○ | DATE OF BIRTH MO DAY YR | COUNTY

CHART OR PATIENT ID NUMBER

CLINICIAN | CLINICIAN'S PHONE # ( ) -

SUBMITTER

NAME OF PERSON COMPLETING THIS FORM | PHONE # ( ) -

MAIL RESULTS TO:

CITY, STATE, ZIP CODE:

COUNTY

AREA CODE & PHONE # ( ) - | FAX # ( ) -

EPIDEMIOLOGY

SPECIMEN IS FROM

○ SINGLE CASE ○ CONTACT ○ OUTBREAK ○ CARRIER

SUSPECTED SOURCE OF INFECTION:

TRAVEL HISTORY (CONTINUE TRAVEL HISTORY IN COMMENTS, IF NECESSARY)

○ FOREIGN ○ USA MO DAY YR TO MO DAY YR

MO DAY YR TO MO DAY YR

VACCINATION HISTORY

COMMENTS

SPECIMEN INFORMATION

ATTENTION: (See Instructions on Reverse Side of Form)

○ BACTERIOLOGY ○ CLINICAL MYCOBACTERIOLOGY
○ MOLECULAR DIAGNOSIS/PCR ○ PARASITOLOGY

SPECIFIC AGENT SUSPECTED: _____

DATE COLLECTED MO DAY YR | TIME OF DAY : ○ AM ○ PM

DATE OF ONSET MO DAY YR | TIME OF DAY : ○ AM ○ PM

DATE SENT TO STATE MO DAY YR | FATAL? ○ YES ○ NO

SUBMITTER'S LAB NUMBER:

○ BLOOD ○ CSF ○ SPUTUM ○ BRONCHIAL WASH
○ SERUM ○ STOOL ○ RECTAL SWAB ○ URINE
○ THROAT ○ GASTRIC ○ URO-GENITAL ○ NASOPHARYNGEAL
○ WOUND (SITE) _____ ○ FLUID (SPECIFY) _____
○ TISSUE (SPECIFY) _____ ○ OTHER (SPECIFY) _____

HAVE SPECIMENS FROM THIS PATIENT BEEN SUBMITTED PREVIOUSLY? ○ YES ○ NO

IS THIS REQUEST INVOLVED IN A MEDICAL-LEGAL SITUATION? ○ YES ○ NO

PLEASE ATTACH YOUR TEST RESULTS:

SPECIMEN SUBMITTED IS:
○ ORIGINAL MATERIAL ○ PURE ISOLATE ○ MIXED ISOLATE

MEDIA USED FOR SUBMISSION OF SPECIMEN (SPECIFY): _____

LABORATORY EXAMINATION REQUESTED:

○ ANTIMICROBIAL SUSCEPTIBILITY ○ SEROLOGY
○ IDENTIFICATION/CONFIRMATION ○ ISOLATION
○ MOLECULAR DIAGNOSIS/ PCR/ MTD ○ PFGE
○ OTHER (SPECIFY) _____

TREATMENT

DRUGS USED	DATE BEGUN	DATE COMPLETED
	MO DAY YR	MO DAY YR
	MO DAY YR	MO DAY YR

FOR PHL USE ONLY

Date/Time Reported:

DOH 302-013 (01/2007)

Washington State Department of Health

State of Washington
Department of Health
PUBLIC HEALTH LABORATORIES
1610 N.E. 150th Street
Shoreline, Washington 98155-9701
Phone: (206) 418-5400
Fax: (206) 418-5545
MTS #1327 CLIA #50D0661453
Http://WWW.DOH.WA.GOV/EHSPHL/PHL

FOR PHL USE ONLY

Lab Number Date/Time Received

Please Print Clearly

SEROLOGY/VIROLOGY/HIV

PATIENT

NAME (LAST)

(FIRST) (MI)

ADDRESS

CITY STATE ZIP CODE

MALE ○ FEMALE ○ | DATE OF BIRTH MO DAY YR | COUNTY

CHART OR PATIENT ID NUMBER

PHYSICIAN | PHYSICIAN'S PHONE # ( ) -

SUBMITTER

NAME OF PERSON COMPLETING THIS FORM | PHONE # ( ) -

MAIL RESULTS TO:

CITY, STATE, ZIP CODE:

COUNTY

AREA CODE & PHONE # ( ) - | FAX # ( ) -

EPIDEMIOLOGY

SPECIMEN IS FROM

○ SINGLE CASE ○ CONTACT

○ OUTBREAK ○ CARRIER

SUSPECTED SOURCE OF INFECTION:

TRAVEL HISTORY (CONTINUE TRAVEL HISTORY IN COMMENTS, IF NECESSARY)

○ FOREIGN ○ USA MO DAY YR TO MO DAY YR

MO DAY YR TO MO DAY YR

VACCINATION HISTORY

COMMENTS

SPECIMEN INFORMATION

ATTENTION: (See Instructions on Reverse Side of Form)

○ SYPHILIS SEROLOGY ○ VIRUS ○ HIV

SPECIFIC AGENT SUSPECTED:

DATE COLLECTED MO DAY YR | TIME OF DAY : ○ AM ○ PM

DATE OF ONSET MO DAY YR | TIME OF DAY : ○ AM ○ PM

DATE SENT TO STATE MO DAY YR | FATAL? ○ YES ○ NO

SUBMITTER'S LAB NUMBER:

TYPE OF SPECIMEN

○ SERUM/BLOOD ○ CSF ○ NP/THR ○ ORASURE

○ OTHER (SPECIFY)

VIRUS EXAMINATIONS

Chief Clinical Findings. (check system involved and list chief symptoms)

○ Respiratory

○ Central Nervous System

○ Cutaneous Eruptions- Location and Type

○ Other

Optimally, collect isolation specimen within 3 days of onset. Submit each specimen as soon as collected. Keep at refigerator temperatures. 24 hour delivery is perferred

SYPHILIS SEROLOGY

Reason For Test

○ **Treatment Control** (VDRL only, Syphilis already confirmed)

○ **Prenatal** (Screen due to pregnancy)

○ **Premarital State** (Required for Marriage LIcense)

○ **Diagnostic/Screen** (VDRL as screen, if reactive TPPA will be performed for confirmation

○ **Reference** (VDRL and TPPA performed, Clinical history indicative of Syphilis)

SYMPTOMS

○ NO ○ YES

(If yes, list symptoms. Check REFERENCE)

PREVIOUS TEST RESULT: (Please list any previous test results pertaining to specimen submission)

○ VDRL ○ RPR ○ OTHER

HIV

TYPE OF TEST REQUESTED: ○ ELISA ○ WESTERN BLOT

PREVIOUS HIV TEST DONE? ○ YES ○ NO ○ DON'T KNOW ○ DECLINED

IF YES, TYPE OF TEST DONE: ○ Conventional ○ Rapid ○ Other

SAMPLE TYPE: ○ Blood -Finger Stick ○ Blood - Venipuncture ○ Blood Spot ○ Oral Mucosal Transudate ○ Other

RESULT: ○ Positive ○ Negative ○ Preliminary Positive ○ Indeterminant ○ Don't Know ○ Declined ○ Not Asked

HAS A PREVIOUS SPECIMEN ON THIS PATIENT BEEN TESTED AT THE STATE LAB?

○ YES ○ NO STATE LAB NUMBER

FOR PHL USE ONLY

Date/Time Reported:

Washington State Department of Health

State of Washington
Department of Health
PUBLIC HEALTH LABORATORIES
1610 N.E. 150th Street
Shoreline, Washington 98155-9701
Phone: (206) 418-5473
Fax: (206) 418-5545
MTS #1327 CLIA #50D0645145

Lab Number | Date/Time Received

FOR PHL USE ONLY

Please Print Clearly **MYCOBACTERIUM TUBERCULOSIS ISOLATES**

PATIENT

NAME (LAST) (FIRST) (MIDDLE)

ADDRESS CITY STATE ZIP CODE

MALE ○ FEMALE ○ | DATE OF BIRTH MO DAY YR | COUNTY | CHART OR PATIENT ID NUMBER

SPECIMEN

SUBMITTER

ADDRESS

CITY STATE ZIP CODE

PERSON FILLING OUT FORM | PHONE NUMBER

SPECIMEN SOURCE:

○ SPUTUM ○ GASTRIC
○ BLOOD ○ URINE
○ BRONCHIAL WASH ○ CSF
○ FLUID (SPECIFY)_____
○ TISSUE (SPECIFY)
○ WOUND (SITE)_____
○ OTHER (SPECIFY)_____

LABORATORY EXAMINATION REQUESTED:

○ ANTIMICROBIAL SUSCEPTIBILITY ○ STOCK ○ MTD
○ PZA ○ PLATE SENSI ○ RFLP
○ OTHER (SPECIFY)_____

SUSCEPTIBILITY RESULTS: (PLEASE CIRCLE)

INH S R STREP S R
RIF S R EMB S R
PZA S R OTHER(SPECIFY)_____ S R

PRIMARY SUBMITTER

ADDRESS

CITY STATE ZIP CODE

COUNTY | PHONE NUMBER

PRIMARY PHYSICIAN | PHONE NUMBER

SPECIMEN WAS RECEIVED AS:

○ REFERENCE ISOLATE ○ CLINICAL SPECIMEN

HAVE SPECIMENS FROM THIS PATIENT BEEN SUBMITTED PREVIOUSLY?

○ YES ○ NO

DATE COLLECTED MO DAY YR

DATE RECEIVED MO DAY YR

SMEAR RESULT AND DATE MO DAY YR POSITIVE NEGATIVE

DATE POS MTB REPORTED MO DAY YR

DATE SENSI REPORTED MO DAY YR

DATE SENT TO STATE LAB MO DAY YR

COMMENTS

FOR PHL USE ONLY

Transfusion-Related Acute Lung Injury (TRALI)

by Linda Parisi, DOH/LQA

Adapted from: Transfusion, Volume 47, July 2007, "How do we investigate and manage donors associated with a suspected case of transfusion-related acute lung injury?" CAP Today, Volume 21, No. 10, October 2007, "Catching, Tracking, and Tackling TRALI."

Transfusion-Related Acute Lung Injury (TRALI) is not a new discovery. It was first described by Mark Popovsky in the early 1980s. TRALI is a complex issue faced by blood collection facilities. To date, there is no detailed uniform approach to managing donors associated with a suspected case of TRALI. It is estimated that one in 50,000 fatalities is due to TRALI. Current knowledge of TRALI suggests that the cause is multifactorial and that there are immune and possible separate or combined nonimmune mediated mechanisms that can result in TRALI. Approximately 89% of the cases reported have an immune-mediated component where human leukocyte antigen (HLA) or neutrophil antibodies have been detected in the donor. The American Red Cross has documented that between 2003 and 2005, 71% of all probable cases resulting in a fatality have involved female donors who were antibody-positive. In 2003, the Food and Drug Administration (FDA) reported the number one cause of transfusion deaths was TRALI. Up until then, the number one cause was transfusing the wrong unit of blood. The syndrome TRALI still maintains a mysterious etiology and it appears that patients who have underlying hematologic diseases, patients who are in the ICU, and patients who are undergoing surgery may have increased risk for TRALI. Evidence is emerging that TRALI is even more common than previously realized.

A common definition of TRALI adopted in 2005 is: A new acute lung injury occurring during or within 6 hours after a transfusion, with a clear temporal relationship to the transfusion or multiple transfusions. Approximately one year ago, the American Association of Blood Banks (AABB) made two recommendations:

1. U.S. blood centers initiate measures to reduce the risk of TRALI in plasma by November 2007, and
2. Initiate measures to reduce the risk of TRALI in apheresis platelets by November 2008.

The AABB recommendations have brought fundamental policy changes which show that the majority of institutions have moved to meeting plasma needs with all-male plasma donors to decrease the number of leukocyte antibodies. Some early studies in the United Kingdom (U.K.) show a dramatic drop in the number of cases of TRALI after switching to an all-male plasma program. However, it will be another year to see the actual U.S. impact of similar policy changes. It may be difficult to determine actual statistics due to underreporting, underdiagnosis, and the lack of centralized data collection. Some experts believe that pooling plasma dilutes the antibodies causing TRALI, but the possibility that CJD variant can be transmitted by transfusion is increased. The U.K. is planning to conduct trials of a platelet additive solution in 2008. This method suspends platelets in an additive solution and plasma, thus diluting the plasma. There is no additive solution available in the U.S. to date. New strategies under discussion could include questioning donors about pregnancy history or testing for HLA antibodies. The questions would be similar to these:

1. Have you ever received a blood transfusion or received human-derived tissue grafts?
2. Female Donors Only: Have you ever been pregnant or had a miscarriage or abortion?

If blood centers went to an all-male platelet apheresis program, there would be a huge shortage of platelets in the U.S. Another mechanism that the AABB is recommending is to educate physicians on appropriate blood utilization. There is evidence that overtransfusing practices are still prevalent, and general education could make a difference.

Adapted from:

Transfusion, Volume 47, July 2007, "How do we investigate and manage donors associated with a suspected case of transfusion-related acute lung injury?"

CAP Today, Volume 21, No. 10, October 2007, "Catching, Tracking, and Tackling TRALI."

LQA Update, continued from page 1

- **Provider Performed Microscopic Procedures (MTSP)**
  - Include the biennial license fee with your application.
  - The nine approved microscopic procedures can only be performed by one of the defined licensed providers.
  - Site can perform tests listed on the FDA waived test list.

If you perform other than Waived or PPMP tests, you quality for one of the following types of license:

- **Categorized (MTSC)** inspected by LQA.
- **Accredited (MTSA)** inspected by a private accrediting organization.

Requests for changes to your MTS/CLIA license: There are new procedures for making changes to an existing MTS/CLIA license. Some of the most common are listed below. Contact the LQA office either by e-mail (find the e-mail addresses on the LQA website) or by calling 206-418-5600 if you have questions.

- **Director Change:** Use the "Change in Director" form found on the LQA website.
- **Lab Contacat Change:** Use the "Change in Lab Contact" form found on the LQA website to change the Lab Contact, Microbiology Contact, and Cytology Contact.
- **Test Menu Change:** Use the "Test Menu Change Notification Form" found on the LQA website. Use this form for test menu or test volume changes for all license categories. The LQA office will contact you if this change results in a license category change.
- **Name, Address, Phone and Fax Number Change:** Use the "Demographic Change Form" found on the LQA website.
- **Change of Ownership:** Complete a new MTS/CLIA license application form (see above).

Training Course: Microscopic Examination of Vaginal Fluid (Wet Mount)

Washington State Public Health Laboratories and University of Washington Seattle STD/HIV Prevention Training Center are sponsoring a training course on the Microscopic Examination of Vaginal Fluid (Wet Mount) on Wednesday, May 28, 2008.

This half-day workshop is designed for healthcare providers, nurses, and laboratory personnel performing vaginal wet mounts. It will focus on specimen handling, performance, and interpretation of microscopic examination of vaginal wet mounts. Discussion will include proper collection of specimens, result reporting, CPT Coding, and quality assurance practices. Participants will perform actual microscopic examination of vaginal wet mounts.

Participants will receive 0.3 CEUs for completion of this course.

There are two classes available for this date. Choose either a morning or an afternoon class time. Please register online at www.seattlestdhivptc.org. The registration fee is $100. If paying by check, make it payable to **University of Washington** and send it to the Seattle STD/HIV Prevention Training Center, 901 Boren Ave, Suite 1100, Seattle, WA 98104. To pay by credit card, go to www.seattlestdhivptc.org and download the Payment by Credit Card form. Complete the form and fax it to 206-221-4945, Attn: Ronnie Staats, before the August 27, 2008 registration deadline. **For more information or an application, please contact** Ronnie Staats at **rstaats@u.washington.edu** or call 206-685-9848.

PHL Specimen Submission Forms

Do you submit specimens to the Washington State Department of Health Public Health Laboratories for testing?

See the article on pages 2-5 for information about changes to this process.

Calendar of Events

PHL Training Classes:
(http://www.doh.wa.gov/ehsphl/phl/training/train.htm)

Basic Course in Urine Sediment
May 15 Shoreline

Shipping & Handling of Infectious Substances
May 20 Shoreline

2008 ASCLS-WA Spring Meeting
April 24-26 Lynnwood

Northwest Medical Laboratory Symposium
October 15-18 Portland

15th Annual Clinical Laboratory Conference
November 10 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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